DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

93117d

MAR 21 2003

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Oliver Leibinger, General Manager
Georg Leibinger
Bahnhofstrasse 59
D-78570 Muhlheim
Federal Republic of Germany

Dear Mr. Leibinger:

We are writing to you because on December 2-5, 2002, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving various models of cranial drills, burrs, trephines, and accessories, manufactured at your Georg Leibinger facility located at Bahnhofstrasse 59, D-78570, Muhlheim, Federal Republic of Germany.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are intended for use in diagnosing or treating a medical condition or to affect the structure or function of the body (Section 201(h) of the Act, 21 U.S.C. § 321(h)).

The Act requires that manufacturers of medical devices obtain marketing clearance for their devices from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that your firm obtained marketing clearance before it began offering your devices for sale. The kind of information your firm needs to submit in order to obtain this clearance is described in the enclosed material entitled "Premarket Notification 510(k) Regulatory Requirements for Medical Devices." The FDA will evaluate this information and decide whether your devices may be legally marketed in the United States.

Because your firm does not have marketing clearance from FDA, marketing cranial drills, burrs, trephines, and accessories is a violation of the Act. The devices are adulterated under

Section 501(f)(1)(B) (21 U.S.C. § 351(f)(1)(B)) and misbranded under Section 502(o) (21 U.S.C. § 352(o)) of the Act. The devices are adulterated under the Act because your firm did not obtain premarket approval based on information developed by your firm that shows the devices are safe and effective. The devices are misbranded under the Act because your firm did not submit information that shows its devices are substantially equivalent to other devices that are legally marketed.

The above-stated inspection revealed that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of these devices are not in conformance with the Quality System (QS) Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These deviations from the QS Regulation cause your devices to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)). Significant deviations include, but are not limited to the following:

a. Failure to assure that when computers or automated data processing systems are used as part of production or the quality system, computer software shall be validated for its intended use according to an established protocol, as required in 21 CFR 820.70(i). For example: (1) The software program, [redacted] that controls the automated manufacturing processes, along with the various manufacturing equipment, has not been tested to an established protocol and has not been validated to assure it is performing to specifications and user needs. (2) The [redacted] software, that is being used to maintain quality system records, such as device history and change control records, has not been validated.

b. Failure to document acceptance activities, as required by 21 CFR 820.80(e). These records shall include: (1) The acceptance activities performed; (2) the dates acceptance activities are performed; (3) the results; (4) the signature of the individual(s) conducting the acceptance activities; and (5) where appropriate, the equipment used. For example, the Device History Records do not include the acceptance activities performed and, where appropriate, the equipment used to perform the activity, such as snap-on tools and handles.

c. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example, functional testing procedures have not been developed and implemented for all devices manufactured.

d. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, written Medical Device Reporting (MDR) procedures have not been developed and implemented.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and

determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

If you fail to take prompt action to correct these deviations, the FDA may take regulatory action without further notice to you. Under Section 801(a) of the Act, for example, your devices could be detained without physical examination upon entry into the United States on the grounds that they appear to be adulterated under Section 501(f)(1)(B) and misbranded under section 502(o). In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

In order to remove the devices from this detention, it would be necessary for you to obtain the required marketing clearance for your devices and to provide a written response to the charges in this Warning Letter for our review. As soon as the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your devices may resume entry into this country.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you receive this letter, the steps you are taking to correct these problems. We also ask that you explain how you plan to prevent these deficiencies from occurring again. If you need more time, let us know why and when you expect to complete your corrections. If the documentation is not in English, please provide an English translation to facilitate our review. Please address your response to:

Mr. Donald W. Serra, Chief
Cardiovascular and Neurological Devices Branch, HFZ-341
Division of Enforcement B
Office of Compliance
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

If you have any questions, please contact the Compliance Officer, Ms. Mary Ann Fitzgerald, at 301-594-4648, extension 130, or you may write to her at the address on this letterhead.

Sincerely yours,

for Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health